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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,420	11/28/2000	Steven K. Yoshinaga	A-579C	7508

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,420	YOSHINAGA ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/09/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *77, 78, 80 and 83* is/are allowed.

6)☒ Claim(s) *56-76, 79, 81, 82, 84, 85* is/are rejected.

7)☒ Claim(s) *83* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Ilia Ouspenski, Group Art Unit 1644, Technology Center 1600.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application (08/09/2004) after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous office Action has been withdrawn pursuant to 37 CFR 1.114.

3. Applicant's amendment, filed 08/09/2004, is acknowledged.

Claims 1 – 55 have been cancelled.
Claims 56 – 85 have been added.

Claims 56 – 85 are pending.

4. Applicant's IDS, filed 08/09/2004, is acknowledged.

It is noted that for certain references, such as, for example, CC and CP, only Table of Contents has been provided. In such cases, only the Table of Contents has been considered by the Examiner.

It is noted that reference CG could not be located in prior applications, and has been lined through. Applicant is invited to resubmit this reference to complete the record. The examiner apologizes for any inconvenience to applicant for having to resubmit the reference.

5. This Office Action will be in response to applicant's arguments, filed 08/09/2004.

The rejections of record can be found in the previous Office Action (mailed 07/14/2003).

It is noted that New Grounds of Rejection are set forth herein.

Rejections of record set forth in the previous Office Action but not reiterated herein have been obviated by Applicant's amendment, filed 08/09/2004.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

6. Claims 60, 61, 63, 84, and 85 are objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Even though these claims are in improper form, the examiner has chosen to examine the claims.

7. Claim 83 is objected to under 37 CFR 1.75 as being a duplicate of claim 80. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

8. Claims 56 – 76, 81 – 82, and 84 - 85 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claims 56 – 59, 69, 72, 74 – 76, and 81 – 82, and claims dependent thereon are indefinite in that they recite an arbitrary protein name, CRP1. While the name itself may have some notion of the activity of the protein, there is nothing in the claims which distinctly claims the protein and "all related polypeptides described herein" (page 41

bottom paragraph of the instant specification). For example, others in the field may isolate the same protein and give such an entirely different name.

Applicant should particularly point out and distinctly claim the CRP1 protein by claiming characteristics associated with the protein (e.g. amino acid sequence, activity, etc.). Claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what that protein is and what the compositions are made up of.

(B) Claims 56 and 57, and claims dependent thereon are indefinite in that they recite the limitation "a nucleotide sequence." There is insufficient antecedent basis for this limitation in the preamble of the claims, as the preamble recites "a nucleic acid molecule."

(C) Claim 85 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential process steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

(D) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

9. Claims 56 – 64, 67 – 69, 72 – 74, 82, and 84 - 85 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The specification discloses that the polypeptides of SEQ ID NO:12 and SEQ ID NO:17 are two forms of a human B7-RP1 polypeptide; and that SEQ ID NO:7 is a mouse B7-RP1 polypeptide.

Applicant's arguments, filed 08/09/2004, with respect to the newly added claims have been fully considered but have not been found convincing. Applicant's arguments are addressed below in the context of the reiteration of the rejection of record in the previous office action (mailed 07/14/2003) as applied to the newly added claims.

The newly added claims recite:
(A) "derivatives" of polypeptides,
(B) polypeptides comprising "percent identity" language, and
(C) polypeptides comprising "fragments".

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for the following reasons:

(A) Claim 61 recites "a polypeptide comprising a derivative of a polypeptide."

As noted in the previous Office Action, the record is not clear as to whether the term "derivative" is limited to a chemical modification (as the first paragraph on page 43

of the instant specification appears to imply) or if it also encompasses amino acid sequence variation.

Until the record is clarified, the rejection of claim 61 is maintained, essentially for the reasons of record.

(B) Polypeptides comprising "percent identity" language.

Applicant's amendment to limit new claims to polypeptides that are "at least about 95 percent identical" and "stimulate T-cell proliferation and/or activation or binding to CRP1," has obviated the rejection of record of claims directed to a genus of polypeptides but do not require any shared testable functional activity.

However, claims 68, 73, and 82 recite polypeptides (or nucleic acid molecules encoding polypeptides) comprising an amino acid sequence that is at least about 95 percent identical to a specified sequence. The specification does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant has not addressed this issue in the response filed 08/09/2004. The rejection is maintained essentially for the reasons of record. The rejection of record is incorporated herein as if reiterated in full.

(C) Polypeptides comprising "fragments".

Applicant requests that the rejection of record be withdrawn since, as the Applicant states, the newly added claims recite fragments or polypeptides having specific sequences. However, new claims 57 – 59, 67, 69, 72, and 74 still recite the "comprising a fragment" language. Therefore, the rejection is maintained for the reasons of record. The rejection of record is incorporated herein as if reiterated in full.

10. Claims 57, 59 – 64, 70, 72 – 74, 79, 81 – 82, and 84 – 85 are rejected under **U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

It is apparent that the amino acid sequence disclosed in GenBank Accession No. AB014553 is required for making and using the claimed invention. However, Applicant has not provided the sequence.

The amino acid sequence is considered essential subject matter to the instant application and the claimed invention.

Applicant has disclosed the sequence GenBank Accession number, however, this is not sufficient for a skilled artisan to envision the sequence referred to in the instant claims. Consequently, conception of the invention cannot be achieved until an appropriate written description of the structural and functional properties of the claimed invention has occurred. Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Applicant is invited to amend the instant specification to provide the essential subject of the amino acid sequence defining the claimed polypeptide, as set forth in GenBank Accession No. AB014553. Further, Applicant is limited to the sequence defined by GenBank Accession No. AB014553 at the time the invention was made.

Applicant is reminded to provide a Sequence Listing which complies with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is further reminded to provide the appropriate Hawkins Declaration to accompany amending the instant specification to provide the amino acid sequence set forth in GenBank Accession No. AB014553.

The following is noted. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

11. Claims 56 – 76, 81 – 82, and 84 - 85 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for "a polypeptide that has an activity of binding to the polypeptide of SEQ ID NO:2," *does not reasonably provide enablement for* "a polypeptide that has an activity of binding to CRP1," whereas CRP1 is defined to encompass "all related polypeptides described herein" (page 41 bottom paragraph).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not appear to provide an enabling definition of the term "CRP1" since "all related proteins described herein," including polypeptides which do not necessarily share substantial structure or function with the polypeptide set forth in SEQ ID NO:2, are encompasses in the description of a "CRP1 polypeptide" disclosed on pages 41 – 42 of the instant specification.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the changes which can be made in "CRP1" and still maintain its function are unpredictable; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

12. Claims 56 – 64, 67 – 69, 72 – 74, 82, and 84 – 85 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for:

Polypeptide "derivatives" which are clearly limited to chemical derivatives (e.g., as recited in claim 62);

Polypeptides consisting of polypeptides having only limited deviation from a reference sequence (e.g., a polypeptide 95% identical over the full length of SEQ ID NO:7, 12, or 17) AND having a testable function supported in the specification as filed (and priority documents);

Polypeptides consisting of fragments of SEQ ID NO:7, 12 or 17 in which the claim language clearly limits the fragments to subsequence of SEQ ID NO:7, 12 or 17;

Does not reasonably provide enablement for:

Polypeptide "derivatives" which are broadly claimed (claim 62);

Polypeptides comprising polypeptides having sequence deviation from a reference sequence, even if a testable function is stated;

Polypeptides comprising fragments of reference sequences unless a particular function can be attributed to a specific fragment.

Applicant states that the newly presented claims are not subject to the rejection of record. However, new claims recite "derivatives" (claims 61), polypeptides comprising "percent identity" language (claims 68, 73, and 82), and polypeptides comprising "fragments" language (claims 57 – 59, 67, 69, 72, and 74). Therefore, the rejection is maintained for the reasons of record. The rejection of record is incorporated herein as if reiterated in full.

Conclusion

13. Claims 77 – 78 and 80 appear to be allowable.

It is noted that claim 83 appears to be free of prior art, but is objected to as being a duplicate of claim 80 (see section 7 above).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

September 22, 2004

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
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9/28/04